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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,152	10/02/2000	Robert C. Gallo	4115-116 DIV 4	4147

23448 7590 05/06/2003  
INTELLECTUAL PROPERTY / TECHNOLOGY LAW  
PO BOX 14329  
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER
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STUCKER, JEFFREY J

ART UNIT	PAPER NUMBER
1648	18

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	Applicant(s)
Examiner	Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on 2/27/03

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

### Disposition of Claims

Claim(s) 40, 42, 44-49, 68, 71, 73, \*82-86 is/are pending in the application.

Of the above claim(s) 45-49, 68, 71, 73 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 40, 42, 44, \*82-86 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

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This Office Action is in response to the amendment filed 2/27/03.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This application contains claims 45-49, 68, 71, and 73 drawn to an invention nonelected with traverse in the amendment filed 11/22/02 in response to a telephone conference on 11/20/02. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The formal drawings filed 2/27/03 are acceptable.

The rejection of claims 40, 42, 44, and 82-86 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

The rejection of claims 40, 42, 44, and 82-86 under 35 U.S.C. 101 because the claimed invention is not supported by either a

credible asserted utility or a well established utility is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that the claimed compositions have been effective in treating the effects of HIV infection, including weight loss, KS lesions, and CD4<sup>+</sup> T cell counts. Applicant further argues that applicants have provided sufficient tests results in the present application to show the efficacy of the claimed composition and methods in humans and animal models with reference to pages 145-152 of the instant specification with the assertion that the compositions of the present invention were tested on SIV infected monkeys and humans infected with HIV. This is not persuasive because the disclosure is not commensurate with the claimed invention. The claims are directed to compositions comprising various fractions purified from hCG containing samples. The specification teaches using hCG in various treatments. The best that can be determined from the disclosure is that hCG has some efficacy. The part of the specification cited only teaches hCG, not the claimed fractions. Assuming, *arguendo*, that  $\beta$ hCG or some fraction has some efficacy for treating the effects of HIV infection, claim 42 is directed a composition "effective in the treatment of HIV infection" which is contrary to applicant's arguments that the claims are directed to

treating the effects of HIV infection rather than HIV infection, *per se*. Therefore, the rejection is maintained.

The rejection of claims 40, 42, 44, and 82-86 under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention is maintained.

Applicant's arguments are not persuasive for the reasons set forth above.

The rejection of claims 40, 42, 44, and 82-86 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

Applicant's arguments are not persuasive for the reasons set forth above.

The rejection of claims 40, 42-44, and 82-86 are rejected under 35 U.S.C. 112, first paragraph, because the specification,

while being enabling for the composition extracted from urine, does not reasonably provide enablement for all "native" sources is withdrawn in view of the amendment to the claims.

The following is a new ground of rejection necessitated by applicant's amendment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40 and 86 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40 and 86 are unclear because the language "at least one fraction" must be changed to "more than one fraction" or "at least two" because the composition requires at least hCG (77 kD) or  $\beta$ hCG (10 kD), and have a molecular weight (MW) of 40, 15, or 3 kD which makes for at least two fractions. The fraction can not comprise hCG or  $\beta$ hCG and have a MW or of 40, 15, or 3 kD.

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The claimed invention is apparently free of the prior art of record.

No claims are allowed.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Unofficial communications may be faxed to: (703) 308-4426.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Jeffrey Stucker*  
JEFFREY STUCKER  
PRIMARY EXAMINER